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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/047,202	01/14/2002	Jiri Zemlicka	WSV-374CPCN	7856

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LAHIVE & COCKFIELD
28 STATE STREET
BOSTON, MA 02109

EXAMINER
BERCH, MARK L

ART UNIT	PAPER NUMBER
1624	9

DATE MAILED: 01/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/047,202	ZEMLICKA ET AL.	
	Examiner	Art Unit	
	Mark L. Berch	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 29-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *33* is/are allowed.

6)☒ Claim(s) *1,29-32 and 34-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The traverse of the requirement for restriction is unpersuasive. Applicants first argue lack of burden. However, as noted, searches in Groups II=VI would entails searches in 546/118, and 544/182, 254, 280, 309, 317 and others. Group VII would even more. For example, if B were an indole, a benzimidazole, or a benzotriazole, there would be searches in assorted places in class 548. If B were a pyrrolopyridine or a triazolopyridine, there would be searches in additional places in class 546.

Applicants argue that "the present restriction is inconsistent with the restriction requirement issued in the parent application." This is mistaken. The parent did not claim any subject matter in groups II-VII, and hence there was no need for a restriction. There was indeed a "partial search of the prior art", but that covered only a small part of the current Group I, as that is all that was claimed in the parent. No search was performed on any aspect of groups II-VIII.

Accordingly, the requirement is made FINAL.

Claims 1, 29-32, and 34-41 are rejected as being drawn to an improper Markush Group. The claims are drawn to multiple inventions for reasons set forth in the above requirement for restriction. This does not constitute an art recognized genus. The claims are examined only to the extent that they read on the elected invention. Cancellation of the non-elected subject matter will overcome the rejection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 29-30, 34-41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6352991. Although the conflicting claims are not identical, they are not patentably distinct from each other because These claims are just a broader version of the claims of the parent.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 35-37 and 40-41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

These claims are drawn to the treatment of viruses generally. No such feat has ever been accomplished. Most antivirals are effective against only one or two viruses.

Although several drugs have been developed which are effective against a handful of viruses, no one has been able to get any of these antiviral drugs to work generally. There are over 400 pathogenic viruses in humans alone, with hundreds more in animals.

Thus, it now includes rotoviruses, especially the Group A type, which commonly lead to osmotic diarrhea in children. It includes calciviruses (e.g. Norwalk, Kawaii, Snow Mountain, etc) which cause gastroenteritis and are so poorly understood that even classification of these is considered poor. It covers measles, which can lead to croup, conjunctivitis and bacterial pneumonia. It covers astroviruses and coronaviruses, including toroviruses, which commonly cause diarrhea. It covers the very dangerous category of enteroviruses, which embrace the three polio viruses, around 30 Coxsackie viruses, a like number of echoviruses as well as other enteroviruses. These cause all manner of paralytic disorders, aseptic meningitis, pericarditis, etc, often with permanent damage or death, and are widespread. Rubella has serious implication for pregnant women. It also embraces reoviruses, which have been associated with encephalitis and pneumonia. It further embraces paramyxoviruses, especially mumps, which can cause edema, orchitis, pancreatitis, meningitis and testicular damage. It covers Parvoviruses, including B19, which can cause fifth disease and arthritis, and can exacerbate a whole range of blood disorders. It covers the Marburg virus, which can produce lesions practically anywhere in the body and Ebola, which is often deadly. It covers herpes viruses such as EBV, HHV-5, HHV-6 , HHV-7, HHV-8, HVS and Simian B virus, which , is capable of infecting simian handlers, causing among other things meningoencephalitis. It covers Parainfluenza, RSV, rabies, New Castle disease, Hepatitis E, hantoviruses, and various vesiculoviruses, which can cause vesicular

stomatitis. It covers alpha viruses, such as Venezuelan encephalitis or the Semliki Forest virus. It covers retroviruses such as HTLV-I, HTLV-II and FeLV. There are also dozens of phleboviruses causing a wide assortment of fevers (e.g. sandfly fever) widespread in southern Europe, middle east and Asia. Other arboviruses of some importance include various tick fevers, and Rift Valley fever. There are all manner of arboviruses which attack the CNS, including, just in the United States, SEF, EEE, WEE, and SE and numerous others elsewhere. It covers the rhinoviruses, the most common cause of the "common cold". It covers all manner of poxviruses.

Under such circumstances, it is proper for the PTO to require evidence that such an unprecedented feat has actually been accomplished, *In re Ferens*, 163 USPQ 609. No such evidence has been presented in this case. The failure of skilled scientists to achieve a goal is substantial evidence that achieving such a goal is beyond the skill of practitioners in that art, *Genentech vs Novo Nordisk*, 42 USPQ2nd 1001, 1006.

The scope of human herpes viruses (claim 37) is likewise not enabled. By way of background, it should be noted that new human herpesviruses continue to be discovered, and now includes 8 human ones. The family is divided into 3 subfamilies. There are the alphaherpesvirinae, which include the simplexviruses HSV-1 and HSV-2 (i.e. HHV-1 and HHV-2), and the genus varicellovirus, Varicella Zoster Virus, i.e. HHV-3. There are the betaherpesvirinae, which include the genus cytomegalovirus, CMV, i.e. HHV-5 and the roseolovirus genus, with HHV-6 and HHV-7. There are the gammaherpesvirinae, which include the genus Lymphocryptovirus, EBV, i.e. HHV-4 and the Rhadinovirus, HHV-8. Herpesviruses are similar is terms of virion structure but are widely separated in terms of genomic sequence and proteins. They have no

common antigens. Their shape is unusually complex. A proteinaceous core has a large DNA genome wrapped around it, all in a toroid shape. This is inside an icosahedral capsid with 162 hexagonal capsomers. Outside this is an amorphous, proteinaceous region called the tegument. Surrounding this is the envelope with at least 9 associated glycoproteins. These proteins appear to be individually dispensable for infectivity, and herpesviruses appear to have available more than one route for penetration.

Although several drugs have been developed which are effective against one or a few human herpesviruses, no one has been able to get any of these drugs to work generally. In the herpes family, in vitro suppression often does not translate into actual usefulness.

Consider for example EBV. This is the virus linked to infectious mononucleosis (IM); nasopharygeal carcinoma; Burkitts lymphoma; Post-transplantation lymphoproliferative disease (PTLD), which exists in 4 B-cell forms and in some T-cell variants as well; and other T-cell lymphomas including Benign Lymphocytosis and Purtillo syndrome; some thymomas; and hairy leukoplakia. There are a few antivirals which will rather weakly suppress EBV replication. However, the skill level in this art is so low, and the difficulty of the task so high, that those skilled in the art are unable to get such drugs, e.g. Acyclovir to provide therapeutic benefit. The most important disease linked to EBV is of course IM, a disorder which is invariably listed as untreatable.

Moreover, there is much more covered here than EBV. HHV-8 is now recognized as a causative agent for Kaposi's Sarcoma, the most important AIDS-related neoplasm. There is no treatment for this.

The claim language of the parent (see patent claim 9) is suggested and would overcome the rejection.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim lacks its structural formula.

Claim 31 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The 4th choice is a molecule, not a moiety, and hence it has no point of attachment. Note how the others end with "-yl". For whichever choice is made for the point of attachment, applicants must show that one of ordinary skill in the art would have known that this choice, and not another, was intended.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 703-308-4718. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 708-308-1235.

Mark L. Berch
Primary Examiner
Art Unit 1624

January 9, 2003